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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/445,656 07/17/00 KABANOV

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000110 HM12/0801
DANN DORFMAN HERRELL & SKILLMAN
SUITE 720
1601 MARKET STREET
PHILADELPHIA PA 19103-2307

EXAMINER

NGUYEN, H

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

08/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

*next
is final*

Office Action Summary

Application No.

09/445,656

Applicant(s)

KABANOV ET AL.

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The claimed priority of this application to U.S. Provisional Application No. 60/053,000, filed on June 13, 1997, through PCT/US98/12139, filed on June 11, 1998 under 37 U.S.C. 371, is acknowledged.

Claims 1-18 are presented for examination.

Abstract objection

This application does not contain an abstract of the disclosure as required by 37

CFR 1.72(b). An abstract on a separate sheet is required.

OK
Moot ✓
App. Submitted an Abs.

Claim rejection

The following is a quotation of the **second paragraph of 35 U.S.C. 112**:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

- Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase "between surfactant hydrophobic groups" is vague. On the one hand, the phrase appears to be superfluous because the surfactants are electrostatically bound to the polymer. On the other hand, it suggests that some surfactant may not be bound to the polymer, but may be bound to the said electrostatically bound surfactant molecules by hydrophobic interactions.

In claim 8, the terms "aspartic" and "glutamic" are misspelled.

In claim 15, the terms "prostaglandins" and "leukotrienes" are misspelled.

Moot OK ✓
correction ✓

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most or correction ✓
In claim 11, line 3, the term "dioloeyl" is vague. It appears to be typographical

error.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbell et al. (US Patent No. 5,410,016) in view of Ahmad et al. (US Patent No. 5,112,611), Nakayama et al. (US Patent No. 5,531,917) and Weiner et al. (US Patent No. 5,171,737).

Hubbell et al. teach block copolymers comprising a water soluble region such as polyethylene glycol and a biodegradable region such as polylactic or polyamino acid (column 7, line 6 and column 8, line 68). Controlled drug delivery of active agents such as enzymes from devices such as microspheres is disclosed (column 10, lines 29-48).

charged
Hubbell et al. do not teach ~~nonionic~~ surfactant having a biological activity.

charged
Ahmad et al. teach papain for aiding human digestion (abstract). Controlled release is disclosed (column 3, lines 7-11).

Nakayama et al. teach the stabilization of a proteolytic enzyme with a surfactant (abstract). Combinations of nonionic, anionic, and amphoteric surfactants are specified (column 2, line 62 bridging column 3, line 12). Papain is disclosed (column 3, lines 17-

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18). Sodium lauroyl sarcosinate and lauryl dimethylaminoacetic betaine are specified (column 5 and 6, Table 1).

Weiner et al. teach dioleoyl phosphatidylethanolamine (DOPE) and dioleoyl phosphatidylcholine (DOPC) as surfactants use for delivery of bioactive agents (abstract, column 2, lines 28-34).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to deliver papain with the device of Hubbell et al to achieve the beneficial effect of aiding human digestion in view of Ahmad et al. and to add surfactants to achieve the beneficial effect of stabilizing the enzyme in view of Nakayama et al.

As to the claimed complex, it is argued that such is inherently formed during mixing of the components to make the obvious composition. As to the particular claimed polyanionic and polycationic segments of the claimed block copolymer, polyaspartic acid and polylysine are well known in the art as commercially available polyamino acids for the Hubbell et al. biodegradable region.

As to the claimed nonionic surfactants, one of ordinary skill would use DOPE or DOPC as such because their utility for delivering bioactive agents in view of Wiener et al.

As to the claimed biologically active surfactant, sarcosine is well known as a metabolic intermediate.

Double patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or

Withdrawn

100-100-100

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discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 2-5, 7-12 and 14-15 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 3-14 of copending Application No. 09/445,656³. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 09/445,656. Although the conflicting claims are not identical, they are

withdrawn
D/C of the
same
filing date

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not patentably distinct from each other because claim 1 of the instant application is encompassed claim 1 of the copending application.

OK withdrawn This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-18 are rejected.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is (703) 605-1198. The examiner can normally be reached on M-F (9:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Edward J. Webman can be reached on (703) 308-4432 or supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Helen Nguyen
Patent Examiner

July 29, 2001

EDWARD J. VERMAN
PATENT EXAMINER
GROUP 1500